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BENEFIT SHARING IN THE NEW GENOMIC MARKETPLACE: EXPANDING THE ETHICAL FRAME OF REFERENCE

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Introduction

Late in the year 2002, two Canadian announcements dramatized key issues in the development of the new genomic marketplace. In November, Canada's Minister of Industry, whose department is responsible for much of the national government's research expenditure, announced a "framework agreement" with the Association of Universities and Colleges of Canada. In return for commitments of additional federal funds for research, university presidents had agreed to double the amount of research performed by universities and triple their "commercialization performance" by the year 2010.¹ A few weeks later, the Supreme Court of Canada ruled that the Harvard mouse or OncoMouse, the first genetically modified mammal to be patented in the United States, was not patentable subject matter in Canada.² This ruling was greeted with consternation by at least some members of the biotechnology research community. The president of the University of Toronto's Innovations Foundation, the university's "Technology Opportunity Company,"³ was quoted as saying: "If you can't patent it, you can't make a company out of it, you just have to dump it into the public domain and you can't get any investment."⁴

These two events are connected by the expanding private sector role in financing medical and life sciences research,^{5,6} and the role played by intellectual property (IP) protection in attracting the private funds that universities and hospitals now regard as indispensable. Lost in much of the public debate about the Harvard mouse was the fact that E.I. du Pont de Nemours & Co. was entitled to an exclusive licence on the mouse as part of the deal that financed 'inventor' Philip Leder's appointment at Harvard.⁷ US federal policy and legislation, especially since the passage of the Bayh-Dole Act in 1980, have facilitated and encouraged the emergence of a new era of commercially aggressive collaboration among universities, private industry and federal funding agencies.^{8,9,10} According to the best available estimates, public and non-profit funding for genomics research in the United States in the year 2000 amount to US \$819.8 million, while private financing was estimated at over US \$1 billion, probably between \$1.5 billion and \$2 billion.¹¹ Comparable data are not available for Canada. However, many national programs for financing research encourage, if they do not require, "partnerships" with the private sector.¹² For example, Genome Canada – a foundation to which Industry Canada has committed C\$300 million – requires that grant recipients obtain at least equivalent funding from their partners. The Canada Foundation for Innovation (CFI), to which C\$3.1 billion has been committed, requires similar matching commitments in many of its funding programs, and is even more explicitly oriented toward commercial applications. The Canadian Institutes of Health Research (CIHR), the national health research granting council with a current annual budget of C\$650 million, offers a variety of opportunities for industry co-sponsorship of training and salary awards as well as research operating grants.¹³

In this paper, I use the term 'biopatenting' to describe the patenting of human biological materials such as cell lines, DNA sequences and the associated proteins, of innovations based on the information contained in human biological materials, and of processes that involve manipulating genetic material for commercial purposes. Examples in this last category include the process components of the patent claims for the Harvard mouse, and stem cell processes related to the production of human tissues and organs *in vitro*. I argue that discussions about sharing the benefits from genomics research, and specifically about biopatenting, must be explicitly linked to an ethical critique of what George Soros, ironically one of the richest men in the world, has called "market fundamentalism."¹⁴ Soros' concern is that market fundamentalism has enhanced the power of financial capital on a global scale in ways that may lead to the destabilization of national economies and international capital markets. Mine is rather with how market norms and priorities are crowding out other values and vocabularies so that the value of research is judged by reference

to the likelihood of commercializable results. At the same time, it has become extraordinarily difficult to challenge the linkage between bioscience and business in setting research directions. Biopatenting policy represents a small, but important element in this larger scale transition.

Questions of how the benefits from genomics research, and medical and life sciences research more generally, should be distributed can be considered on at least three levels. The first level involves the claims of individuals whose tissues, or whose distinctive genetic characteristics, have been used in research that leads to commercial products. The second level involves the claims of populations that have contributed to research that yields commercializable results, whether by providing actual biological materials or by making possible the detailed documentation of pedigrees. The third level involves allocation of the benefits from research and its commercial products, independently from considerations of individual or group contribution to research, across national borders and boundaries of other kinds that are defined by race, gender, and especially economic situation.

A number of thoughtful contributions to the literature have addressed ethical concerns related to benefit sharing at the first two levels,^{15,16,17,18,19} even though proposed solutions often have not been acted upon. I concentrate here on the third level, to which less attention has been paid in recent discussions. At this level, which involves engagement with various areas of public policy, an eclectic and transdisciplinary approach to ethical analysis is required. Reflecting my own background in political theory and political economy, I concentrate here on issues related to distributive justice. Others might take a different approach. The generic methodological point is that responsible ethical analysis must not regard crucial background elements of the social and economic context – such as the expanding role for private financing of scientific research – as ‘too big to change’. Instead such elements must be exposed to sustained critical analysis, of the kind bioethics now applies mostly to micro-level questions in the clinic or the laboratory.

Biopatenting, distributive justice, and market fundamentalism

Patents are now routinely issued on human genes and their protein products throughout the industrialized world, with patent protection often extending to include a broad range of uses for the identified gene, although it remains to be seen whether the broad claims in any number of recent biopatents will stand up to legal challenges. Similarly, genetically modified mammals are considered patentable subject matter in the United States and elsewhere in the industrialized world.²⁰ Patents have been issued, as well, on important process technologies such as those used in the ‘creation’ of the Harvard mouse and, at least in the United States, on human stem cells and methods of producing and using them.^{21,22,23,24} (The process claims in the Harvard mouse patent were never contested in Canada.)

The standard defence of the current expansive approach to biopatenting runs as follows. Private investment in research is essential because of the high costs involved in conducting therapeutically useful research, and in moving new research findings from the laboratory bench to the marketplace as useful diagnostic or therapeutic products. Investors demand strong intellectual property (IP) protection before they are willing to commit the necessary resources; indeed, a portfolio of patents may represent the principal asset of small and medium-sized firms. Without that protection, investment will not flow into research and its commercialization. The results will include not only a loss of jobs, scientific talent and (potentially) export revenues as investment flows to other jurisdictions, but also failure to realize the exciting health benefits associated with advances in bioscience.

Each element of this line of argument deserves more detailed examination. In the industrialized world, the availability of public support for scientific research is not constrained by scarcity in any absolute sense, but rather by competing political priorities. In Canada, governments have made a political choice to give higher priority to other objectives, such as cutting taxes, and to tie available research support more closely than in the past to the needs of industry in a knowledge-based economy.²⁵ As a result, efforts to attract foreign investment have assumed special importance. Thus, Industry Canada lists among the country’s attractions for biotechnology investors not only the availability of research support through a variety of federal programs, but also the concentration of patient populations in fourteen major urban catchment areas and a patient base that is “multi-ethnic, with significant pockets of founder population groupings,” as well as the pending streamlining of clinical trial regulations.²⁶

As an empirical observation, the point about what investors will and won’t do is probably accurate, as far as it goes. This is why balancing the need to offer returns to investors against many other legitimate goals and

expectations represents a complex ethical and policy challenge. However, just as the level and direction of public support for research is a matter of political choice, so commercialization of advances in the life sciences that offer genuine health benefits need not be contingent solely on the anticipation of adequate profitability. For example, public or non-profit institutions that would have the option to forgo market rates of return in order to achieve the social benefit of broader access to important tests and therapies are not *a priori* implausible, although their compatibility with the current generation of trade agreements may be open to question. Canada had such an institution (Connaught Laboratories, established by the University of Toronto in 1914), until it was sold to France's Institut Mérieux in 1989 by the Government of Canada, which had purchased it from the university. Subsequent changes of ownership enabled the transnational pharmaceutical giant Aventis to (in Aventis' own words) "become the world leader in vaccines." When publicly funded advances in genomics research offer genuine health benefits, the option of production for the public interest rather than solely for private profit may become especially attractive.

The strength of IP protection may be an important ingredient in a country's ability to attract life scientists and the private funds to support them, but especially in Canada and other countries whose domestic markets are relatively small, we must ask *why* this should be so. Wherever research is carried out, the important health care markets now and in the near future will be the United States and the European Union (EU), so those are the jurisdictions where patent protection is most important for commercial purposes. Likewise, the location of development and manufacturing would seem to owe at least as much to geography and other aspects of the business environment as to the local availability of patent protection. Ownership of capital has always given investors substantial leverage with respect to national and subnational governments.²⁸ The removal of many barriers to cross-border trade and investment flows ('globalization') has enhanced that leverage in a way that one commentator describes as "a return to property-based voting rights, but on an international scale."²⁹ It seems likely that large corporations, in particular, use the choice of where to finance and locate their research activities as a form of "job blackmail"³⁰ aimed at securing favourable policies from national governments not only in IP but also in a variety of other areas. This point was implicitly conceded by the Canadian Biotechnology Advisory Committee (CBAC), an advisory body appointed by Cabinet, when it noted that: "Canada may suffer economically if it does not follow its major trading partners (United States, European Union countries and Japan) in permitting patents on higher life forms ... This difference with its major trading partners may create the impression that Canada is unfriendly toward biotechnology, thus impeding international investment in Canada's biotechnology industry. While this latter concern relates more to Canada's business reputation than to patent law, it is a relevant consideration in determining Canada's patent policy."³¹

CBAC's observation leads to the question of whether biopatenting policy is primarily about better health through research, or about other things. Evidence is accumulating that the breadth and proliferation of recent biopatents threatens both health research and clinical practice. Uncertainty about the legal reach of 'upstream' patents means that prudent researchers (or researchers who report to risk-averse senior managers) must locate and negotiate with multiple patent holders, and patent provisions may restrict access to the very advances that are used by the pharmaceutical and biotech industries to illustrate the glowing promise of their activities.^{32,33,34} The temporary monopoly provided by a patent enables its holders (a category that may include the inventors themselves, the research institutions that employ them and the firms to which the patent is licensed) to charge what the market will bear. This may not be problematic in the case of a new kind of fuel injector or furnace. However, the high price that patents on the BRCA 1 and BRCA 2 genes enable Myriad Genetics, Inc. to charge for its test of hereditary susceptibility to breast cancer,^{35,36} and the reduced availability of hemochromatosis testing in the United States because of patent concerns,³⁷ are almost certainly early warnings of multiple controversies to come. For example, a recent report for the Ontario Ministry of Health observed that "the patenting of stem cells may well mean that exclusive royalty fees will have to be paid in the future for replacement organs and tissues developed in this manner."³⁸ For all but the most zealous enthusiasts of unrestricted markets, such prospects raise questions about when public policy may legitimately limit economic returns to inventors and investors, in order to shift the terms of the social contract represented by the grant of a patent in favour of access to knowledge and products that may save lives.

A more basic uncertainty involves the link between innovation – the Canadian policy buzzword of choice with respect to research support – and health benefits. Does the fact that a new product is successful in the health care marketplace mean that the research that produced it was the best use of available resources? Quite apart from issues of distributive justice raised by the fact that the weight of one's 'vote' in the marketplace is directly proportional to the size of one's wallet, identifying the most worthwhile research by looking for the most successful products ignores the potential for market failure in cases where not all the benefits from health research can be privately marketed (such benefits, in the terminology of economics, represent 'positive externalities'). As a rule, neither research on the

determinants of health nor the refinement and replication of interventions to alter those determinants generates a product or service that can be packaged and sold. Little evidence exists that, on a society-wide basis, focusing public sector research support on areas with commercial potential will yield more substantial health benefits per dollar than (for example) expenditures on improving our already considerable understanding of the social determinants of health. For that matter, little evidence exists to support choices about the appropriate tradeoffs between investing in any form of research and investing in interventions that make use of the existing knowledge base to improve the determinants of health at the population level. Those interventions might, for instance, aim at preventing injuries, controlling tobacco use, or turning the tide of obesity that now alarms researchers because of its longer term implications for population health and health care costs.^{39,40}

The analytical problem is that in most cases, this question cannot be answered reliably until after the fact. The political problems are far more constraining. The quest for high-tech solutions is congruent not only with what might be called the ‘gladiator’ model of health care, which emphasizes the heroic battle against diseases with clearly identifiable victims, but also with the building of profitable businesses. If the primary objective of health research expenditure is to maximize population health benefits, Canada and the United States may well be allocating too much of their societies’ total resources to life sciences research that is motivated by the anticipation of commercially valuable results. They are probably not over-investing in such research if the primary objective is to create and sustain a profitable industry, but that objective may or may not have much to do with maximizing health: private returns and social returns are not at all the same thing.

This misallocation may become more serious as the role of private research financing continues to expand. Conversely, our societies are almost certainly under-investing in preventive interventions with a high probability of effectiveness.⁴¹ Indeed, the current scope and reach of biopatents may create substantial impediments to research on preventing illness, at least in the absence of much clearer research exemptions.^{42,43,44} An equally disturbing longer term prospect is that institutionalizing the link between research funds and commercial opportunities will mean that researchers whose areas of interest have modest commercial possibilities are cut off from the most important sources of research support. Ultimately, they may be screened out of research institutions and careers altogether. Social scientific investigation of whether this is already happening should be undertaken with some urgency.

Commercialization and biopatenting in a global context

If the link between health benefits and commercializable research is questionable when considered within the boundaries of the rich countries, it is fragile in the extreme when considered in a global context. Any serious discussion of sharing benefits from scientific research on a global scale must therefore begin from the fact that in the world as it is now, some people’s lives are worth vastly less than others’, based on the resources that are available to protect their health. Roughly half the world’s population lives on less than US\$2 a day,⁴⁵ and the least developed countries spend an average of US\$11 per person per year on health (public and private expenditures combined).⁴⁶ Markets simply do not work very well for the poor when it comes to health, or anything else.

Global inequalities of income and wealth have three sets of implications for benefit sharing. The first has to do with the general consequences of IP protection for economic development.⁴⁷ “Many of today’s advanced economies refused to grant patents throughout the 19th and early 20th centuries, or found legal and illegal ways of circumventing them” even as they used various stratagems to limit industrial competitors’ access to their technologies.⁴⁸ However those same economies, led by a United States determined to protect the technological lead of its information technology and pharmaceutical industries,^{49,50} have now entrenched harmonization of IP protection across industrialized and developing countries in the Trade-Related Aspects of Intellectual Property (TRIPs) Agreement.⁵¹ The TRIPs Agreement, which emerged from the Uruguay round of multilateral trade negotiations that also resulted in the creation of the World Trade Organization (WTO), appears to provide a ‘level playing field’ for rich and poor countries. However, the industrialized economies have a tremendous head start in almost every scientific field, and they are of course dramatically richer than the rest of the world.^{52,53}

Second, harmonized IP protection has important implications for access to health care. The authors of the year 2000 United Nations *Human Development Report* provocatively concluded that TRIPs may conflict with international human rights agreements that recognize the right to share in scientific progress, because it “dramatically reduces the possibilities for local companies to produce cheaper versions of important life-saving drugs.”⁵⁴ The ethical

implications of interaction between IP protection and economic disparity were highlighted in the recent, and complex, controversy over the pricing of patent-protected antiretroviral drugs for treating HIV infection in poor countries.⁵⁵ An intensive international campaign by non-governmental organizations (NGOs) eventually led a coalition of pharmaceutical firms, which had strong support from the US government, to abandon legal action claiming that provisions of a law aimed at reducing the costs of essential drugs were contrary not only to TRIPs but also to the property rights provisions of the South African constitution.^{56,57} The positions taken by industry and government are beyond dispute, although it can plausibly be argued that with respect to sub-Saharan Africa as a whole, patent protection actually represents a less significant obstacle to access to essential medicines than more basic issues of finance and infrastructure.⁵⁸

The NGO campaigns contributed to an important statement (the so-called Doha Declaration) from the 2001 WTO Ministerial Conference, which acknowledged the need for “flexibility” on IP issues in such cases.^{59,60,61} What TRIPs actually requires and permits national governments to do when balancing patent protection and public health will only be known as conflicts either wend their way through the WTO dispute settlement process or are negotiated outside it. Thus, the controversy over pricing and production of antiretrovirals may be repeated with respect to any number of patented findings from genomics research, *if* those findings are relevant to diseases that affect rich and poor alike. HIV-AIDS is such a disease; some of its victims in the rich world offer an attractive market and possess a degree of political sophistication that probably gives them influence out of proportion to their numbers. That is why the antiretroviral therapies that became the focus of controversy became available in the first place. No comparable populations suffer from trypanosomiasis, schistosomiasis, or malaria.

Thus, we come to a third set of implications for benefit sharing. The underfunding of lines of research that are promising in terms of their health implications, but are unlikely to be commercially important, has especially serious implications for the developing world. On a global scale “money talks louder than need” in setting priorities for scientific research.⁶² People working in the field of international health are familiar with the so-called 90/10 divide in health research, in which more than 90 percent of global health research expenditure is directed toward diseases that affect the richest 10 percent, or less, of the world’s population.^{63,64} The reason is simple: in a profit-driven research environment, the poor lack the market power that would promise attractive potential returns on investment, so diseases that afflict them are neglected.^{64,66,67}

Administratively feasible policy measures to address the 90/10 gap can be devised, as the Global Forum on Health⁶⁸ is now trying to do. Especially creative is the proposal that potential contributions to health in the developing world should be one of the criteria used by granting councils in setting funding priorities and ranking individual applications.⁶⁹ Such measures are necessary to address issues of distributive justice at the global level, but they will not be sufficient given current distributions of income and wealth. A recent review of drug development over the past quarter-century found that only 16 of 1393 new compounds that had received regulatory approval were for diseases of the poor (tropical diseases and tuberculosis), and noted: “Although substantial advances in molecular biology and pathophysiology have been made—including the ongoing genome sequencing of the parasites that cause malaria, leishmaniasis, and African trypanosomiasis—these advances are not translating into new products directed at the needs of patients. More is known and published on the biology of leishmania and trypanosomes than any other parasite, yet virtually no products result from this wealth of knowledge.”⁷⁰ The basic problem remains that of insufficient market power. Exercises like a recent effort to identify the ‘top ten’ biotechnologies with the potential to improve health in developing countries⁷¹ are of limited value if they do not directly confront this problem ... and the (unsupported) claim in the summary report of this study that “[e]nforcement of intellectual property rights will be crucial to the affordability of these technologies”⁷² borders on the bizarre. The most immediate need in international health, clearly identified by the director-general of the World Health Organization and confirmed by WHO’s Commission on Macroeconomics and Health, is for a several-fold increase in the resources that are available to provide access to basic health care and public health interventions that are available *today*.^{73,74}

Whither benefit sharing? The enclosure analogy and the possibilities for ethics

Fortunately, the position that biopatenting is ethically neutral⁷⁵ now has fewer adherents,^{76,77} and in Canada a long overdue public discussion of benefit-sharing and other ethical issues may be generated by the recent Supreme Court decision. In its final report on patenting higher life forms and related issues, CBAC recommended the development of “policies and practices that encourage the sharing of the benefits of research involving genetic materials,” but did not explore the range of such mechanisms in any detail.⁷⁸ The report as a whole was seriously weakened because its draft version merely set out a taxonomy of positions on the ethics of biopatenting, but its authors did not describe and evaluate the arguments underlying those positions.⁷⁹ Perhaps predictably, the final report concluded that most “social and ethical concerns” (an interesting portmanteau category) were best dealt with outside the *Patent Act*. Two important exceptions, which have not so far been acted upon, involve the report’s recommendations for a clarified research and experimental use exemption and the establishment of a time-limited opposition procedure for challenging the validity of a patent.⁸⁰

A report prepared for Ontario’s Ministry of Health on behalf of Canadian provincial governments, which are concerned not only with attracting industry to their jurisdictions but also about the implications for health care costs in Canada’s system of public health insurance, was much more emphatic about the need for policy attention to the cost and distributional consequences of biopatenting.⁸¹ It called for amendments to the *Patent Act* not only to limit the scope of biopatents when they involve diagnostic tests and therapies, but also to provide for compulsory licensing of genetic diagnostic and screening tests. Ontario’s Ministry of Health has, in fact, rejected Myriad Genetics’ demand that the province’s hospitals stop providing (at much lower cost) predictive genetic tests that, according to Myriad, are covered by its patents.^{82,83}

Otherwise, little action has occurred in response to the federal and Ontario reports, or to numerous proposals from other sources. These proposals include an ethics review process (a “moral tollbooth”) that would operate in parallel with patent examination, although the proposal focuses on the form rather than the content of ethics review.⁸⁴ Ethics review might include ‘upstream requirements’ having to do, for example, with how biological materials were obtained in the research leading to the innovation for which a patent is sought.⁸⁵ In order to address issues of distributive justice in the pricing of patented tests and therapies, the idea has been mooted of a mandated patent licensing society that would make gene inventions available to all users at a fixed royalty rate⁸⁶ – a form of compulsory licensing broader than that envisioned in the Ontario report.

For purposes of the research ethics approval that is critical to research in university settings, distributive justice and benefit sharing as they relate to biopatenting remain effectively off limits. A joint policy of the three federal granting councils⁸⁷ (the Tri-Council Policy Statement) provides a framework for ethics review of research supported by the councils. The review is conducted by research ethics boards (REBs) appointed by the managements of individual research institutions; review of research that receives no such financing is at the discretion of institutions and sponsors. The section of an earlier draft of the Policy Statement that addressed benefit sharing, specifying that “researchers and REBs [research ethics boards] must endeavor to distribute equitably the potential benefits of research,”⁸⁸ was removed from the policy by the granting councils before its adoption. The policy specifies that potential conflicts of interest arising from possible financial benefit to researchers must be disclosed to research subjects. It otherwise provides no basis for ethics review of the content of IP arrangements that may exist among researchers, institutions and sponsors; the substantive portions of the policy make only one reference to IP, dealing with the specialized issue of implanted medical devices. When I have suggested at conferences that the substance of such arrangements is a legitimate topic for ethics review, the idea has been met with incredulity.

On the broader ethical implications of the expanding role of commercial priorities in Canada’s health science research agenda, silence reigns. This may change as a result of the decision by CIHR to participate in a multi-agency Global Health Research Initiative. If the participants in this initiative take seriously the real prerequisites for improving population health on a global scale, the result could be a genuine effort to incorporate potential health benefits outside the borders of the industrialized world into funding criteria. Over the longer term, this initiative could in turn lead to more general debate about the ethical implications of the links between science and business that are exemplified by Canadian genomics research. Where and how this questioning might take place remains uncertain. To date, biotechnology policy has been dominated by the executive branch of the national government, including

agencies like CBAC and the granting councils. Lacking, it seems, is a “public square” in which an informed and critical debate could occur.⁸⁹

Opponents of biopatenting, and of the commercial biotechnology enterprise as a whole, sometimes draw an analogy with the enclosures and extinguishment of customary rights that transformed the pattern of English agriculture and landholding in the eighteenth century and the early nineteenth.^{90,91,92} One consequence was to enrich the landholding few while creating tremendous hardship for the many who depended on access to common lands and on the resources provided by such practices as gleaning (collecting grain left behind after the harvest).^{93,94} The enclosure analogy is most clearly appropriate when applied not to biopatents that are directly related to human health, but rather to crop plants developed from genetic material obtained in developing countries access to which is then, in effect, sold back to people in the country of origin at premium prices.^{95,96} Despite its limitations, the analogy is useful and provocative for at least two reasons.

First, biopatenting, like the enclosure movement, involves the reshaping of law to define and defend forms of property that are newly valuable, or perhaps only conceivable, as a result of advances in science and technology. Yesterday, those advances involved new techniques of farming (such as the continuous rotation of crops), stock breeding, textile production (thus altering the relative returns from crop and pasture land) and land improvement. Today, they are exemplified by the isolation and purification of human genes. Genomics-based industry, in turn represents just one element of an emerging complex of knowledge based industries, and biopatenting may best be understood as part of a more comprehensive redefinition of intellectual property rights that is actually more familiar from the reinterpretation and extension of copyright protection for the digital age.⁹⁷

Second, whatever ethical reflection and on-the-ground resistance may have been associated with enclosures, both were relentlessly swept aside as law and policy responded to the demands of the powerful. Perhaps a similar pattern will emerge in the case of biopatenting, and in other areas of law related to the success of bioscience-based industries. This is the hyper-realist position taken by the author of a recent article on the regulation of genetic research, who concluded that: “Industrial strategy, both on the national and international level, will not be arrested by moral difficulties.”⁹⁸ Concerns about biopatenting underscore the need for Canada to develop policies and institutions that reconcile the need to build internationally viable knowledge-based industries with explicit attention to “moral difficulties” and the appropriate role of commercial considerations both within and across national borders.

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